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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,886	01/31/2004	Yinong Yang	UAF-03-14	8057

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EXAMINER	
KUMAR, VINOD	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/768,886	YANG ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *11-25,29,30,33,34,37,39-41,43 and 45-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,26-28,31,32,35,36,38,42 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/13/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-10, 26-28, 31, 32, 35, 36, 38, 42, 44 and 47 in the paper filed on December 5, 2005 is acknowledged. Applicants arguments filed on December 5, 2005 have been fully considered but they are not persuasive. Applicant argue that the subject matter of the claims is sufficiently interrelated for all claims to be examined together (response; page 4, lines 17-24 and page 5, lines 1-2). Alternatively, Applicants argue that the restriction requirement into IX Groups is improper because the search for subject matter of claims directed to Groups I, II, V and IX overlap with one another (response; page 5, last paragraph and page 6, first paragraph), and like wise search for subject matter of claims directed to Groups III, IV, VI, VII, VII and IX also overlap with one another (response; page 6, second paragraph). The examiner maintains that restriction requirement is proper because literature search requires an extensive analysis of technical information divergent between Groups I-IX and would impose a serious search burden, if done together as described in the Office Action mailed on November 3, 2005. Accordingly, claims 1-10, 26-28, 31, 32, 35, 36, 38, 42, and 44 are examined in this Office Action and claims 11-25, 29, 30, 33, 34, 37, 39-41, 43, 45, 46 and 48-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions. Elected claims must be amended to remove non-elected subject matter. It is noted that claim 47 was erroneously placed in Group I, as it appears in Group IX. As claim 47 does not belong in Group I, it will not be examined. This restriction is made FINAL.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed December 13, 2005 is attached to the instant Office Action.

The listing of references in the specification (pages 33-41) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP Â§ 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The disclosure is objected to because of the following informalities:
Description of drawings do not refer to sequences that appear in the drawing by their sequence identifiers as required by 37 CFR 1.821(d). For example, the five sequences in Figure 1A must be referred to by their sequence identifiers either within the drawing or its brief description. If the sequences appearing in the specification do not have sequence ID numbers assigned to them, then an amendment to the sequence listing will be required as well. There must not be any new matter submitted, therefore it is important to be careful to include only the sequences that are already disclosed in the current specification.

Figure 3 legend on page 5 does not explain what is represented by the abbreviations, "*Avr*" and "*Vir*". The descriptions of Figure 3 should be amended to recite those labels. See 37 CFR 1.74.

The term --invention-- needs to be inserted between the terms "present also" in line 5 on Page 4.

The term "transitional" should be replaced by --transcriptional-- in lines 24 and 30 of Page 12.

The symbol "?" in line 24 of Page 7 needs to be deleted.

Appropriate corrections/clarifications are required.

Claim Objections

4. Claims 8, 26, 27, 35, 38, 42 and 44 are objected to because of the following informalities:

In claim 8, "association" should be --associated--.

In claim 42, the article, --a-- needs to be inserted in line 2 after "with"; In line 3, "the" should be replaced with --a--; In line 5, --the—should be inserted after "isolating"; In line 5, --the—should be inserted after "isolating".

In claim 27, line 2, insert --the-- before "amino" and --a-- before "MAPK5".

Claims 26, 35, 38 and 44 are objected to for depending from non-elected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26, 31, 35 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "continuous cell line", which is confusing as it is unclear what is intended. The specification does not define "continuous cell line". It is unclear how "continuous cell line" is different from other cell lines.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "nucleic acid sequence that encodes a MAPK5 ortholog nucleic acid sequence", which is confusing as it is unclear what is intended. Is the nucleic acid sequence a DNA sequence that encodes an RNA transcript? Or should the term "encode" actually be --comprises--?

Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "A seed produced by a transgenic plant", which is confusing, since it is unclear whether the seed comprises the MAPK5 ortholog nucleic acid. It is suggested that the recitation, --wherein said seed comprises said nucleic acid encoding the MAPK5 ortholog-- be inserted at the end of claim.

Corrections/clarifications are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7, 8, 9, 10, 26, 27, 31, 35, 36, 38, 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic plant with increased stress tolerance and a method of producing said transgenic plant

comprising over-expression of a rice nucleic acid sequence as defined in SEQ ID NO: 1 encoding a MAP kinase 5 (MAPK5) polypeptide as defined SEQ ID NO: 2, does not reasonably provide enablement for a transgenic plant with increased stress tolerance or a method of producing said transgenic plant comprising over-expression of any nucleic acid sequence encoding any MAPK5 or MAPK5 ortholog isolated from any source. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a transgenic plant transformed with a nucleotide sequence operably linked to a regulatory sequence and encoding a polypeptide consisting of MAPK5 ortholog, wherein overexpression said polypeptide in said transgenic plant increases tolerance to abiotic stress compared to a wild type plant, or wherein said nucleotide sequence is from a monocot, or wherein abiotic stress could be temperature, drought or salinity, or a seed produced from said transgenic plant, or a method for enhancing tolerance to abiotic stress in a plant comprising transforming a plant with any MAPK5 nucleic acid

The specification describes isolation of a rice nucleic acid encoding the OsMAPK5 polypeptide (SEQ ID NO: 2), a transgenic plant and a method of producing said transgenic plant with increased stress tolerance comprising over-expression of said nucleic acid. The specification also describes increased MAPK5 (SEQ ID NO: 2) phosphorylation activity in transgenic plants over-expressing SEQ ID NO:2 during abiotic stress response.

Claims 27, 31, 35, 36, 38, 42, 44 and 47 encompass any nucleic acid sequence encoding amino acid sequence of any MAPK5 or ortholog thereof, wherein over-

expression of said nucleic acid results in increased tolerance to abiotic stress. Prior art teaches that although members of MAPK subfamilies have been implicated in stress and defense responses, their exact function remain elusive. The function of MAPK cascade in cell is frequently pleiotropic, and disruption or overexpression of a MAPK gene can generate nonspecific effects. See Zhang et al. (Trends in Plant Science, 6:520-527, 2001).

Specification does provide guidance of over-expressing OsMAPK5a nucleic acid from rice as defined in SEQ ID NO: 1, encoding the MAPK5 polypeptide as defined in SEQ ID NO: 2, in a transgenic plant, making the plant abiotic stress tolerant. However, specification does not teach other MAPK5 kinases or orthologs thereof as encompassed by the claims that can be used in the method to produce the claimed abiotic stress tolerant transgenic plant. Page 10, line 14-16 describe OsMAPK5b cDNA, an alternatively spliced cDNA that encodes an incomplete MAP kinase, that lacks functional activity and thus can not be used in a method to produce abiotic stress tolerant transgenic plant upon over-expressing in a transgenic plant. The specification (pages bridging 9-10) describes MAPK5 ortholog as any functional equivalent of any MAPK5. The function of MAPK cascade in cell is frequently pleiotropic, and disruption or overexpression of a MAPK gene can generate nonspecific effects. See Zhang et al. (Trends in Plant Science, 6:520-527, 2001). The claims encompass any member of MAPK gene family, which are implicated in diverse cell signaling responses including stress and defense as taught by Zhang et al. All MAPK5 orthologs would therefore not increase abiotic stress tolerance in transgenic plants, in the absence of further guidance.

Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as any MAPK5 or ortholog thereof would encompass more than single amino acid changes of the encoded polypeptide as defined in SEQ ID NO: 2. Thus there is a lack of specific guidance in the specification as to how any MAPK5 nucleic acid encoding for MAPK5 polypeptides or orthologs thereof can be used in a method to produce abiotic stress tolerant transgenic plant. It would be highly unpredictable to guess that any nucleic that encodes for MAPK5 polypeptide or ortholog thereof obtained from any source would actually be able to produce abiotic stress tolerant phenotype upon over-expression in a transgenic plant, given that prior art clearly teaches that MAPK is a complex gene family and their over-expression in a cell can lead into non-specific effects. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 7, 8, 10 and claims dependent therefrom encompass any host cell transformed with a nucleic acid sequence encoding a polypeptide as defined in SEQ ID NO: 2. The specification does not describe the use of transforming a host cell other than bacteria or plant cell with a nucleic acid sequence encoding said polypeptide. Undue experimentation by one skilled in the art is required to make use of expressing a said polypeptide in a host cell other than bacteria or plant cell, as MAPK5 is a plant protein.

Given the breadth of the claims, unpredictability of the art and lack of guidance in the specification, as discussed above, undue experimentation would be required by one

skilled in the art to make and use of claimed invention. Therefore, it is maintained that the claims are not commensurate in scope with the teachings of the specification.

7. Claims 27, 31, 35, 36, 38, 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a transgenic plant transformed with a nucleotide sequence operably linked to a regulatory sequence and encoding a polypeptide consisting of MAPK5 ortholog, wherein overexpression said polypeptide in said transgenic plant increases tolerance to abiotic stress compared to a wild type plant, or wherein said nucleotide sequence is from a monocot, or wherein abiotic stress could be temperature, drought or salinity, or a seed produced from said transgenic plant, or a method for enhancing tolerance to abiotic stress in a plant comprising transforming a plant with any MAPK5 nucleic acid

The specification describes isolation of rice nucleic acid molecule encoding OsMAPK5 polypeptide (SEQ ID NO: 2), transgenic plant and a method of producing said transgenic plant with increased stress tolerance comprising over-expression of said nucleic acid. The specification also describes increased MAPK5 (SEQ ID NO: 2) phosphorylation activity in transgenic plants over-expressing SEQ ID NO:2 during abiotic stress response.

Specification describes over-expressing MAPK5 (OsMAPK5a) nucleic acid molecule from rice as defined in SEQ ID NO: 1, encoding the MAPK5 polypeptide as defined in SEQ ID NO: 2, using said nucleic acid molecule in a method to produce

abiotic stress tolerant transgenic plant. However, specification does not describe the structures of large number of nucleic acid molecules encoding MAPK5 kinases or orthologs thereof as encompassed by the claims to produce an abiotic stress tolerant transgenic plant. The specification does not describe the structures of adequate number of species of the broadly claimed genus MAPK5 or orthologs thereof. In view of the fact that prior art teaches that although members of MAPK subfamilies have been implicated in stress and defense responses (Zhang et al., Trends in Plant Science, 6:520-527, 2001), their exact function remains elusive. The specification does not describe the structures of their broadly claimed genus that are correlated to the function of conferring abiotic stress tolerant phenotype when over-expressed in a transgenic plant other than for nucleic acid encoding SEQ ID NO: 2.

Furthermore, the disclosure of SEQ ID NO: 1 encoding SEQ ID NO: 2 is not a consensus representative of other MAP5 sequences from other sources. Thus there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine allelic functional variants, orthologs, paralogs etc. of other sequences, or even other MAPK5 sequences, from another plant species or an organism would produce the desired phenotype when overexpressed in a transgenic plant.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed.

Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Wen et al. (Plant Physiol., 129:1880-1891, 2002).

The claims are broadly drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 1 encoding a polypeptide consisting of amino acid sequence of SEQ ID NO: 2, or wherein a recombinant vector, expression vector or a host cell comprising comprising said nucleic acid molecule.

Wen et al. teach rice *OsMEK1* cDNA encoding a polypeptide OSMEK1 that is identical to instant SEQ ID NO: 2. See Figure 1 and its legend on Page 1882 referring to GenBank Accession No. AF216314. The reference also teaches isolation of a rice *OsMEK1* cDNA clone (same as expression or recombinant vector) isolated from a cDNA expression library, encoding a polypeptide OSMEK1 that is identical to instant SEQ ID NO: 2. The *OsMEK1* cDNA is operably associated with a promoter comprising regulatory nucleotide sequence containing transcriptional and translational regulatory information that controls expression of said cDNA in a host cell.

Accordingly, Wen et al. anticipated the claimed invention.

9. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wen et al. (NCBI, GenBank, Sequence Accession No: AF216314, Pages 1-2, Published December 2000).

The claims are broadly drawn to an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1, or wherein SEQ ID NO: 1 encodes a polypeptide consisting of amino acid sequence of SEQ ID NO: 2, or wherein said isolated nucleic acid molecule is a cDNA or RNA.

Wen et al. teach a nucleotide sequence that is identical to instant SEQ ID NO: 1, encoding a polypeptide identical to SEQ ID NO: 2. See pages 1-2.

Accordingly, Wen et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-10, 26-28, 31-32, 35, 36, 38 are 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wen et al. (Plant Physiol., 129:1880-1891, 2002) in view of Valvekens et al. (PNAS, 85:5536-5540, 1988).

The claims are broadly drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 1 encoding a polypeptide consisting of amino acid sequence of SEQ ID

NO: 2, or wherein a recombinant vector, expression vector or a host cell comprising said nucleic acid molecule, or a transgenic plant transformed with a MAPK5 nucleic acid encoding a polypeptide consisting of amino acid sequence of MAPK5 ortholog, wherein overexpression said polypeptide in said transgenic plant increases tolerance to abiotic stress compared to a wild type plant, or wherein said nucleotide sequence is from a monocot, or wherein abiotic stress is temperature, drought or salinity, or a seed produced from said transgenic plant, or a method for enhancing tolerance to abiotic stress in a plant comprising transforming a plant with any MAPK5 nucleic acid

Wen et al. teach rice *OsMEK1* cDNA encoding a polypeptide OSMEK1 that is identical to instant SEQ ID NO: 2. See Figure 1 legend on Page 1882 referring to GenBank Accession No. AF216314. The reference teaches isolation of a rice *OsMEK1* cDNA clone (same as expression or recombinant vector) isolated from a cDNA expression library, encoding a polypeptide OSMEK1 that is identical to instant SEQ ID NO: 2. The *OsMEK1* cDNA is operably associated with a promoter comprising regulatory nucleotide sequence containing transcriptional and translational regulatory information that controls expression of said cDNA in a host cell. See Page 1881, 2nd paragraph of column 1 through the end of first paragraph of column 2. The reference further teaches that nucleic acid encoding OSMEK1 polypeptide is induced during abiotic stress. See Page 1880, Abstract; Page 1882, Figure 1A; Page 1883, Figures 2, 3; Page 1885, Figure 4A; Page 1886, Figures 5 and 6; Page 1888.

Wen et al. do not teach a transformed plant cell or plant or a method of producing a transformed plant cell or plant.

Valvekens et al. teach a method of transformation of plant cells, comprising cloning a nucleic acid of interest in a binary vector, transforming said vector into host

Agrobacterium, introducing of said vector into plant cell through *Agrobacterium* infection comprising said vector, and regeneration of transgenic plants expressing heterologous protein of interest. See page 5536, column second through column 1 of page 5537; page 5538, Figures 3 and 4.

It would have been obvious to one of the ordinary skill in the art to express the nucleic acid sequence encoding a polypeptide as taught by Wen et al. in plants, using any appropriate plant transformation method, including the method of transforming a plant cell and regenerating a transgenic plant as taught by Valvekens et al. Given that Wen et al. teach that expression levels of OsMAP1 are up-regulated during abiotic stress treatment, one of ordinary skill in the art would have been motivated to express a nucleic acid sequence encoding MAPK5 (SEQ ID NO: 2), in a transgenic plant cell and a transgenic plant, for the purpose of producing an abiotic stress tolerant transgenic plant. It would also have been obvious to produce seeds of the transgenic plant containing the transgene for the purpose of propagation.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER